BLANKETROL® II

OPERATION MANUAL

The operator must read and understand the **Operation Manual** in its entirety prior to operating the equipment.

Cincinnati Sub-Zero Products, Inc., reserves the right to make equipment changes and improvements which may not be reflected in this manual.

CAUTION

Federal law restricts this device to use only on the order of a physician.

DANGER

- Notify the physician if the patient's temperature is not responding properly or does not reach the temperature prescribed in the prescribed time or if there is a change in the prescribed temperature range. Failure to inform the physician of the deviation may result in injury to the patient.
- Do not use the Blanketrol II system in the presence of flammables. **Risk of explosion can result.**
- Power interruption will cause the Blanketrol II to revert to **CHECK SETPOINT** resulting in no therapy to the patient. Follow instructions for desired mode to resume operation. **Failure to resume therapy could result in serious injury or death.**

CAUTION

- **Use** distilled/sterile water only. **Failure to use distilled/sterile water may result in poor performance and damage to the Blanketrol II.**
- **Do not** use De-ionized Water. The majority of de-ionizers do not maintain a neutral pH of 7. If the de-ionized water is acidic, it will cause a battery effect and the copper refrigeration line will begin to deteriorate and cause a leak in the refrigeration system.
- **Do not** use alcohol. Alcohol may cause blanket deterioration.
- **Do not** operate without water to avoid damage to internal components.
- **Do not** overfill. Overfilling may result in overflow when the water in the blanket drains back into the system when the system is turned off.

WARNING

- A physician's order is required for setting blanket temperature and use of equipment. At least every 20 minutes, or as directed by physician, check patient's temperature and skin condition of areas in contact with blanket; also, check blanket water temperature. Pediatric, temperature-sensitive, patients with vascular disease, and operating room patients should be checked more frequently. **Notify the physician promptly of any change in order to avoid serious injury or death.**

- The method of temperature control provided by all hyper-hypothermia units presents the danger of heating or cooling body tissues, particularly the skin, to a point where they are injured, i.e., burns or frostbite, respectively. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.

- Prevent excessive and/or prolonged tissue pressure and shearing forces, especially over boney prominences, to prevent skin damage that may result.

- Do not place additional heat sources between the patient and blanket. **Skin damage may result.**

- The area between the patient and the blanket should be kept dry to avoid injury to patient.

- Use only YSI 400 series, or equivalent, probes on CSZ equipment. **Failure to do this will cause incorrect temperature readings.**

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SECTION 1. INTRODUCTION

1-0. GENERAL SAFETY PRECAUTIONS

To provide the patient maximum safety during the use of the BLANKETROL II hyper-hypothermia system, a thorough knowledge, understanding of the system, the correct application and operating use of the system is required. Each person who is responsible for the use or the direction of the use of the system, such as physicians, nurses, technicians and operators must read and understand this operating manual all precautions and warnings prior to use. It is recommended this manual be reviewed at least semi-annually as a refresher to safe operation and application.

1-1. GENERAL DESCRIPTION OF THIS MANUAL

This manual describes the operation, maintenance, and service of the CSZ BLANKETROL II hyper-hypothermia system. Section One describes the physical and functional characteristics of the BLANKETROL II System. Section Two describes how to prepare the BLANKETROL II unit for general use. Section Three describes how to operate the unit in the Manual Control Mode, Automatic Control Mode, and Monitor Only Mode.

This manual is prepared for professional personnel who use the equipment for patient care. It is designed to be stored with the BLANKETROL II unit and to be readily available for reference when operating the BLANKETROL II System.

1-2. GENERAL DESCRIPTION OF THE BLANKETROL II SYSTEM

The CSZ BLANKETROL II, Model 222R Hyper-Hypothermia System is used to either lower or to raise a patient's temperature and/or maintain a desired patient temperature through conductive heat transfer. The CSZ BLANKETROL II unit is composed of a heater, a compressor, a circulating pump, and a microprocessor board. This unit requires no field adjustments or calibrations in order to maintain the precise measurement of temperature and temperature safety limits.

1-2. GENERAL DESCRIPTION OF THE BLANKETROL II SYSTEM (cont'd)

Water is heated or cooled and pumped from the unit to a blanket. The blanket* rests under and/or on top of the patient and is designed so that the water circulates through the blanket and returns back to the unit.

If cooled water is circulated through the blanket, the desired effect is to reduce the patient's temperature. If warmed water is circulated through the blanket, the desired effect is to elevate the patient's temperature.

The BLANKETROL II unit can be set so that it operates based on the temperature of the circulating water (Manual Control) or it can be set so that it operates based on the temperature of the patient (Automatic Control).

* The recommended blanket(s) for use is described in Section (1-5.)

1-3. CLINICAL APPLICATIONS

The BLANKETROL II unit is used primarily in hospital Intensive and Coronary Care Units, in Operating, Recovery and Emergency Rooms, in Burn Units, and on Medical/Surgical floors. This hyper-hypothermia system can be used with adult and pediatric patients to produce normothermia by lowering a patient's elevated temperature or raising a patient's sub-normal temperature. It can also be utilized to maintain normal body temperature (normothermia) during surgical procedures.

Surgically, this system can be used to produce moderate to profound hypothermia for such procedures as amputations, cardiopulmonary by-pass surgery, vascular surgery, and intracranial surgery. Medically, this system can be used to decrease the rate of circulation, to reduce intracranial pressure, to control cerebral edema, and to reduce oxygen requirements. This system is also used in the treatment of burns, shock, cardiac arrest, and gastrointestinal hemorrhage.

1-4. PHYSICAL DESCRIPTION OF THE BLANKETROL II UNIT

The BLANKETROL II unit is a compact unit with the following physical features:

Dimensions: 17 inches (43.2 cm.) Wide x 17 inches (43.2 cm.) Deep x 36 inches (90 cm.) High

Weight: 131 pounds (59.4 kg.)

Cabinet Construction: Powder coated steel with plastic top. Dual reservoir. Bottom air discharge. Molded-in handle. Bumper guards. Storage compartment. Four 5 inch conductive, swivel type casters.

1-4.1. EXTERNAL FEATURES - FRONT VIEW

The external features in Figure (1-1) of the BLANKETROL II unit are described as follows:

A. The control panel is composed of pressure sensitive touch switches and four LED displays. An expanded description of the control panel is presented in Section (1-4.4.).

B. The operating instructions are printed directly below the control panel. This layout is designed to increase the operator's efficient use of the unit.

C. The power switch is a bevel rocker switch labeled ON at the top and OFF at the bottom. The switch lights up green when ON. A circuit breaker is built into the switch to protect against overload conditions.

D. The storage drawer tilts out from the top to provide storage space for items such as probes, connector cables, connecting hoses, the drain hose, and the Operator's Manual.

E. The grille permits air to be drawn into the unit and pass over the condenser. The air is then discharged through the bottom of the unit. The grille should be kept from being blocked by being cleaned regularly as described in Section (4-4.) of the Operation/Technical Manual.

F. The protective bumper guard surrounds the lower edge of the unit and protects the unit as well as the walls.

G. Four conductive, swivel casters are specially designed to permit the unit to move easily and to prevent it from tipping.

H. The Celsius/Fahrenheit selector switch, abbreviated C/F, is a rocker switch that permits the operator to select the measurement scale, Celsius or Fahrenheit, by which the unit functions. Celsius is in the down position and Fahrenheit is in the up position.

I. The water fill opening is where the operator pours distilled/sterile water to fill the reservoir.

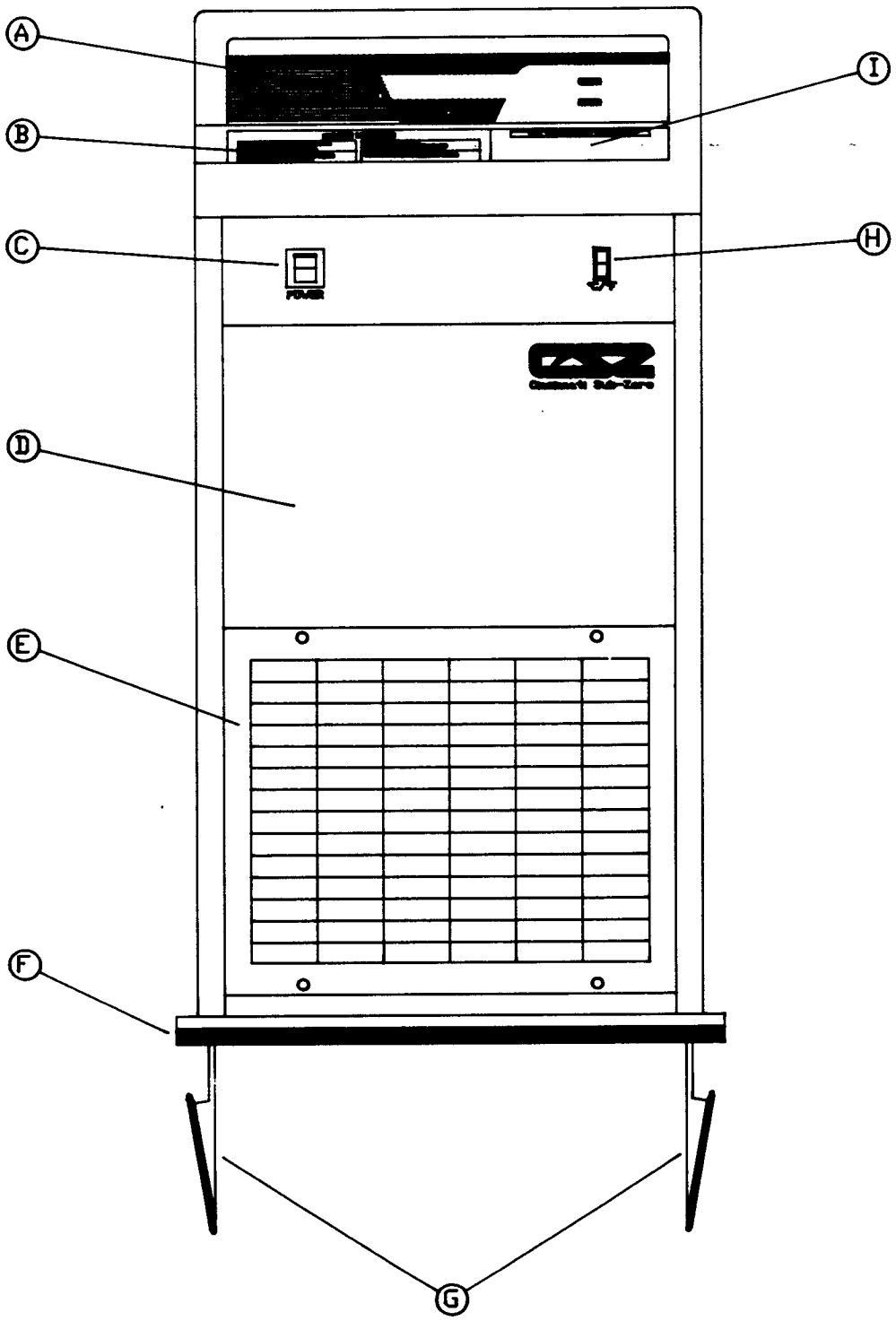

FIGURE 1-1 BLANKETROL II, FRONT VIEW

1-4.2. EXTERNAL FEATURES - RIGHT SIDE VIEW

The external features in Figure (1-2) of the BLANKETROL II unit are described as follows:

A. The water flow indicator is a paddle-wheel in the path of the circulating water with a window to the outside. As water is circulated through the system, it must pass over the paddle-wheel causing it to spin (like a pinwheel). The water flow indicator provides a visual display of the general rate at which the water is circulating. For example, if the unit is circulating water but the connecting hose is pinched, the circulation of the water is restricted. The change in water flow decreases the speed of the paddle-wheel.

When the problem of the pinched connecting hose is solved, an increase in water flow can be seen by watching the water flow indicator increase in speed. A total obstruction of the water path will cause the paddle-wheel to stop completely.

B. The molded-in handle permits the operator to grip the unit when moving it.

C. Two capped screws on the right and left side of the unit secure the top to the base.

D. The patient probe jack is where the Y.S.I. 400 series probe is connected to the unit. Only one patient probe can be connected at a time.

E. Three female, quick-disconnect return couplings on the top row are designed for water to flow in when the male coupling of the connecting hose is attached.

F. The three male quick-disconnect outlet couplings on the bottom row are designed for water to flow out when the female coupling of the connecting hose is attached.

G. The power cord with a hospital-grade 3-prong plug should only be inserted into a properly grounded hospital grade receptacle for 115/100 VAC units and 220/240 VAC units. Electrical Specifications are described in Section (1-7.).

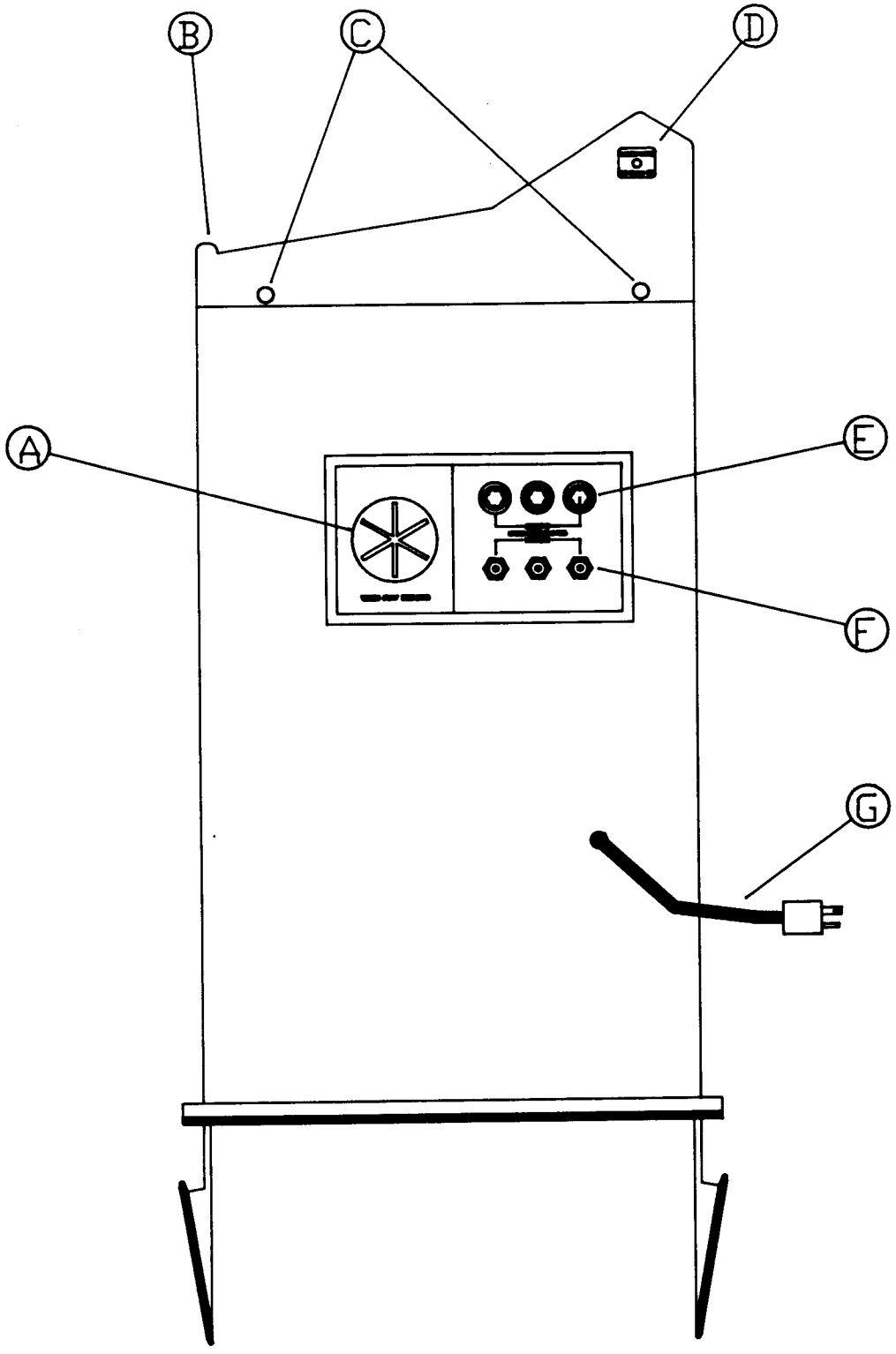

FIGURE 1-2 BLANKETROL II, RIGHT SIDE VIEW

1-4.3. EXTERNAL FEATURES - REAR VIEW

The external features in Figure (1-3) of the BLANKETROL II unit are described as follows:

A. The maintenance label outlines the periodic checks for the BLANKETROL II unit.

B. The specification label outlines the BLANKETROL II unit's electrical requirements.

C. Two air vents provide air circulation for the microprocessor.

D. The nylon strap is used to secure and store the coiled power cord when not in use.

E. The rear enclosure panel secured with four screws provides access to the interior. The panel is removed to perform maintenance, repair, or replacement of components.

F. The serial number label is permanently attached and located along the bottom of the unit on top of the bumper guard.

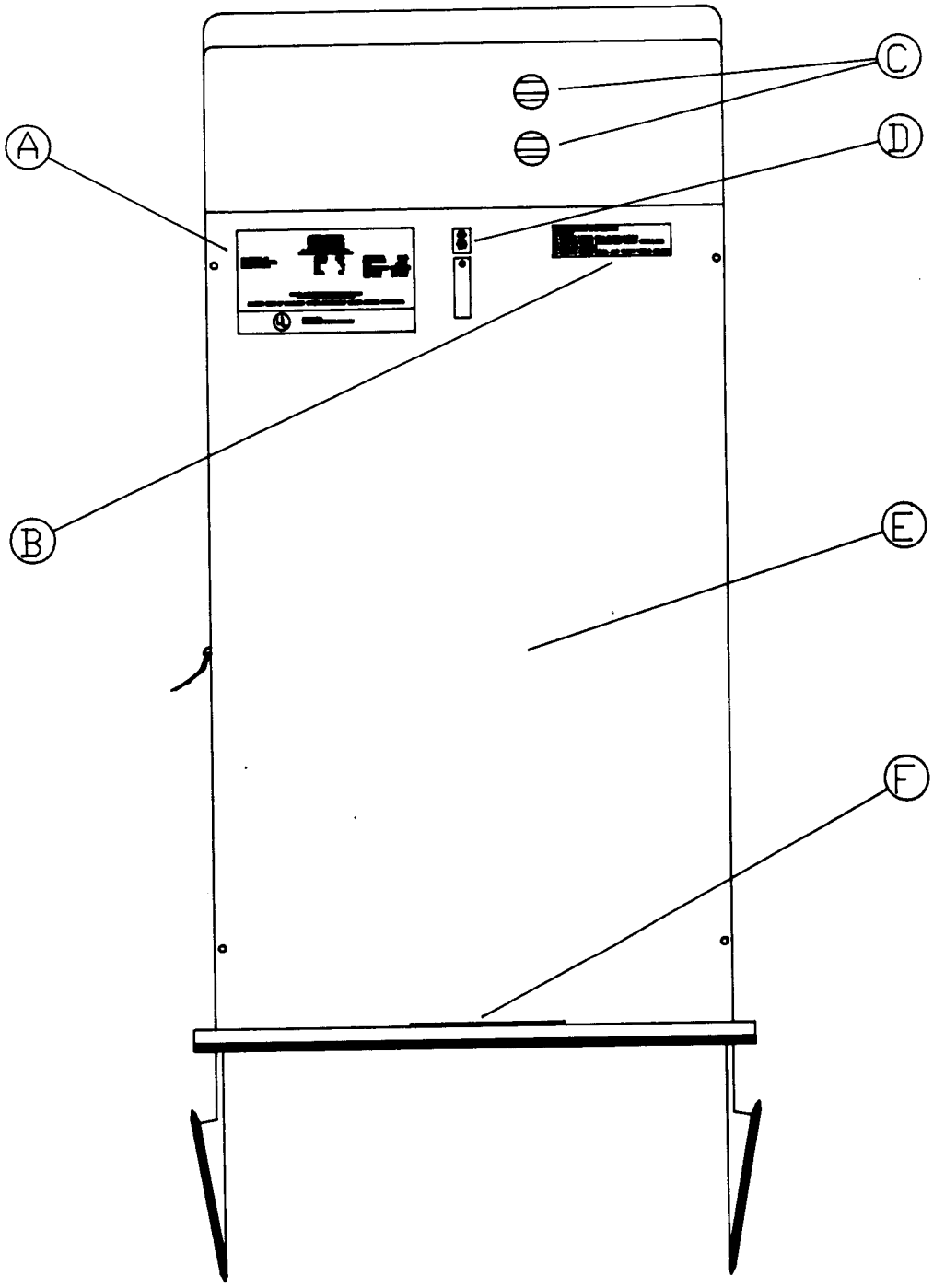

FIGURE 1-3, BLANKETROL II, REAR VIEW

1-4.4. EXPANDED DESCRIPTION OF THE BLANKETROL II CONTROL PANEL

The control panel as shown in Figure (1-4) is composed of pressure sensitive touch switches and LED displays.

The control panel is layed out as follows:

A. On the left hand side, the green digital display labeled BLANKET/WATER shows the actual temperature of the circulating water. The MANUAL CONTROL switch is used to activate the unit so that operation is based on the temperature of the circulating water relative to the Setpoint temperature.

B. In the middle, the digital display labeled SETPOINT shows the desired temperature of the water or the patient as set by the operator. The TEMP SET switch and the Up and Down arrow switches are used to set the Setpoint display. The green arrow on the left of the Setpoint display, the orange arrow on the right of the Setpoint display, the Celsius indicator, and the Fahrenheit indicator are only visible under specific conditions. When visible, each indicator acts as a guide for the operator.

C. On the right hand side, the orange digital display labeled PATIENT shows the actual temperature of the patient. The AUTO CONTROL switch is used to activate the unit so that operation is based on the temperature of the patient relative to the Setpoint temperature.

D. The two switches labeled TEST INDICATORS and SILENCE ALARM are used to confirm that all the indicators on the control panel are working and to silence the alarm in certain conditions.

E. The display labeled STATUS reports the status of the unit and/or indicates changes that the operator should make. The possible status displays are listed in Section (3-8.). Below the Status display are the three LED's colored green, yellow, and red (left to right) that light up depending on whether the unit is cooling, at setpoint, or heating. A REMOVE FROM SERVICE indicator is located below the LED and is visible only if the unit malfunctions in a manner that could be dangerous to the patient and is not Operator Correctable.

F. The MONITOR ONLY switch is used to set the unit to monitor the temperature of the patient without heating, cooling or circulating the water.

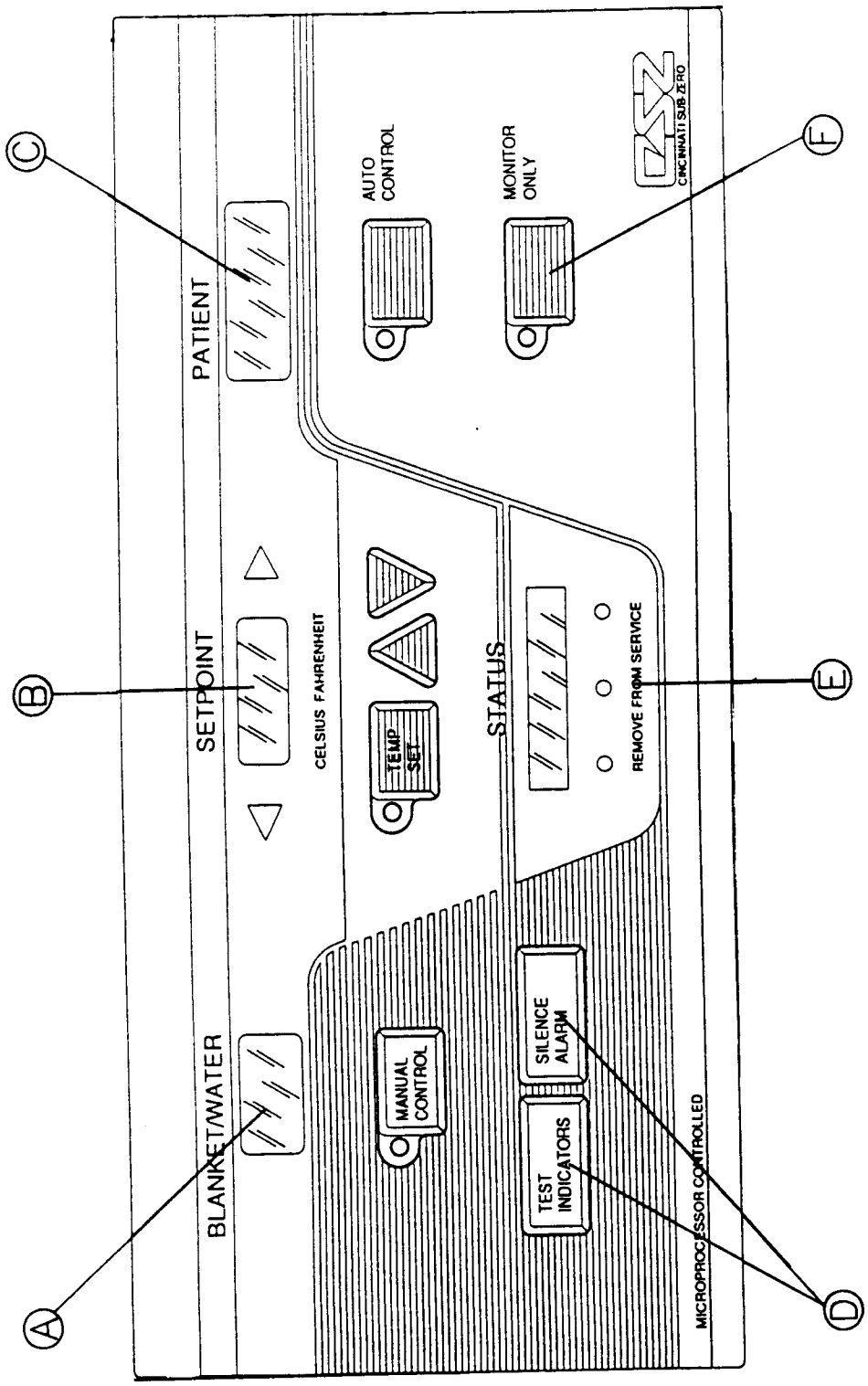

FIGURE 1-4, BLANKETROL II, CONTROL PANEL

1-5. REQUIRED ACCESSORIES

Operation of the BLANKETROL II unit requires the use of the blanket(s) designed to circulate warm or cool distilled/sterile water, a connecting hose with quick-disconnect male and female couplings, and a YSI 400 series thermistor probe (if Automatic Control Mode is to be utilized). BLANKETROL II System Equipment and accessories are listed in Figure 3-1.

CSZ offers the widest selection of hyper-hypothermia blankets to serve your needs providing both reusable and single-patient use blankets. The reusable blanket, the lightweight PLASTIPAD®, comes with an integral nine foot extension hose with quick-disconnect, error proof male and female couplings. A single-patient use blanket, MAXI-THERM®, and a reusable connecting hose are also available. All CSZ blankets offer significantly higher thermal transfer capability than any other brand of hyper-hypothermia blankets.

CSZ also offers a disposable blanket cover, the DISPOSA-COVER™, that guards against stains, helps prevent cross-contamination, enhances patient comfort, provides a moisture barrier, saves on nursing time, and offers greater economy because it prolongs blanket life and reduces laundry costs.

Only a Yellow Springs Instrument Company (YSI) 400 Series probe, REUSABLE or STERI-PROBE™ single-patient use, should be used with the BLANKETROL II unit. If a SINGLE-PATIENT probe is used, a REUSABLE CONNECTOR-CABLE is required in order to connect the disposable probe to the unit. The type of probe may be a rectal/esophageal or skin surface probe.

Operation of the BLANKETROL II unit requires the use of distilled/sterile water or a distilled/sterile water-bacteriostatic agent preparation as described in Section (2-4.).

NOTE: DO NOT USE DE-IONIZED WATER.

Draining the BLANKETROL II unit requires the use of a drain hose with a female coupling. This hose is included in the packaging of the unit and can be retained in the storage compartment of the unit.

1-6. FUNCTIONAL DESCRIPTION OF THE BLANKETROL II SYSTEM

In the Manual Control Mode, the operator sets the desired temperature of the circulating water. The unit either heats or cools the water to reach the desired setpoint temperature. The water circulates through the blanket and either raises or

1-6. FUNCTIONAL DESCRIPTION OF THE BLANKETROL II SYSTEM (cont'd)

lowers the temperature of the patient. In this case, the patient's temperature must be closely monitored. There is no constant relationship between the temperature of the circulating fluid and the temperature of the patient or the change in temperature of the patient. In the Automatic Control Mode, the operator sets the desired temperature of the patient. In addition, the operator must either attach to or insert into the patient a YSI 400 Series probe. The probe plug is then inserted into the BLANKETROL II unit. The probe is used to measure the actual temperature of the patient and this measurement is then compared with the desired Setpoint temperature by the unit's microprocessor. If the actual patient temperature is lower than the desired patient temperature, the BLANKETROL II unit heats the circulating water so that the temperature of the patient is elevated to reach the desired Setpoint. At Setpoint, the unit continues to circulate the water but the heater ceases to operate. When the patient's temperature falls outside the Setpoint range, the heater/compressor resumes operation, heating/cooling the water until the patient's temperature is once again at Setpoint.

If the actual temperature is higher than the desired patient temperature, the BLANKETROL II unit cools the circulating water so that the temperature of the patient decreases to the desired Setpoint temperature. At Setpoint, the unit continues to circulate the water, but the compressor stops. When the patient's temperature falls outside the Setpoint range, the compressor/heater resumes operation, cooling/heating the water until the patient's temperature is once again at Setpoint.

In addition, the BLANKETROL II unit can be set to operate in a Monitor Only Mode. In this mode, the YSI 400 Series probe is attached to or inserted into the patient. The probe plug is then inserted into the Blanketrol II unit. The operator then sets the BLANKETROL II unit to monitor and display the patient's actual temperature. In this mode, the unit does not heat, cool, or circulate the water.

1-6.1. HEATING SYSTEM

The BLANKETROL II heating system consists of an immersion heater, water temperature control, and three high temperature safety devices. Temperature ranges are described in Section (1-6.4.).

The immersion heater is located in the circulating reservoir. The water circulating in the reservoir flows around the immersion heater and is warmed. The heating system is operational in the Manual Control or Automatic Control Modes whenever the control system calls for an increase in the temperature of the circulating water. It is important to note that the rate of change in the circulating water temperature is not directly proportional to the rate of change in the temperature of the patient.

1-6.2. COOLING SYSTEM

The BLANKETROL II cooling system is composed of a compressor, a condenser, a condenser fan, an evaporator coil, water temperature control, solenoid valve, hot gas bypass valve, and three low temperature safety devices. Temperature ranges are described in Section (1-6.4.).

The refrigerant of the cooling system flows through the evaporator coil located in the circulating reservoir. The water circulating in the reservoir flows over the evaporator coil and is cooled.

The cooling system is operational in the Manual Control or Automatic Control Modes whenever the control system calls for a decrease in the temperature of the circulating water. It is important to note that the rate of change in the circulating water temperature is not directly proportional to the rate of change in the temperature of the patient.

1-6.3 CIRCULATING SYSTEM

The BLANKETROL II circulating water system is composed of a magnetically driven circulating pump, a dual compartment reservoir, a water filter, quick-disconnect fittings, connecting hose, and hyper-hypothermia blanket(s).

The 2 gallon (7½ liters) capacity dual compartment reservoir is composed of the circulating reservoir situated under and connected to the replenishing reservoir. When the operator fills the reservoir with distilled/sterile water *, the circulating reservoir fills first and holds approximately ½ gallon (1.9 liters) of water. The remaining 1½ gallons (5.6 liters) are held in the replenishing reservoir. The water moves from the replenishing reservoir to the circulating reservoir by gravity drain as needed.

The circulating water flows over and around the heating/cooling element located in the circulating reservoir. The heated or cooled water then flows out of the reservoir to the circulating pump, through the pump housing, through connecting hoses over a water temperature sensor to the hyper-hypothermia blanket(s). The water circulates through the blanket(s) and returns to the unit. The water then passes through the water flow indicator, through the water filter and returns to the circulating reservoir to be reheated or recooled and then recycled.

In addition, the circulating reservoir contains a low water level sensor which shuts down the unit and sounds the alarm if the water level drops below a preset amount. The unit becomes operational again after the water level is restored to normal.

* Alternate water preparations are described in Section (2-4.)

NOTE: DO NOT USE DE-IONIZED WATER.

1-6.4. TEMPERATURE SAFETY CONTROL SYSTEM

The BLANKETROL II unit is designed to carefully measure and control the temperature of the circulating water. The unit is engineered so that when the temperature of the circulating water reaches the desired setpoint temperature, the unit operates between heating and cooling the water in order to maintain the setpoint temperature. The unit is designed not to exceed or fall below the desired temperature.

As a safety precaution, the BLANKETROL II unit has three high temperature safety devices and three low temperature safety devices. Figure (1-5.) summarizes the high and low temperature limits.

Each safety device continuously monitors the temperature of the circulating water and almost any possible failure is protected by a back-up system. As an additional precaution, if the water temperature sensor itself should fail, the unit shuts down and indicates REMOVE FROM SERVICE. With this safety design, both the patient and the unit are protected from injury or damage caused by extreme temperatures.

At the same time, the operator must regularly monitor the patient whenever hyper-hypothermia therapy is used.

SAFETY CONTROLS FOR PROTECTION FROM HIGH TEMPERATURE

Circulating water reaches 42°C ± .5°C (107.6°F ± 1°F) microprocessor board shuts off heater.

Circulating water reaches 44.6°C ± 1°C (112°F ± 2°)F, safety device shuts off heater, status display flashes "HI TEMP" and the microprocessor board beeper is sounded.

Circulating water reaches 46°C ± 2°C (115°F ± 4°F), back-up safety device shuts off the unit and indicates REMOVE FROM SERVICE, HI LIMIT.

SAFETY CONTROLS FOR PROTECTION FROM LOW TEMPERATURE

Circulating water reaches 4°C ± .5°C (39.2°F ± 1°F), microprocessor board shuts off cooling system.

Circulating water reaches 3°C ± 1°C (37°F ± 2°F), microprocessor board shuts off cooling solenoid and indicates "LOW TEMP."

Circulating water reaches 1°C ± .5°C (34°F ± 1°F), back-up safety device shuts off the unit and indicates REMOVE FROM SERVICE, LOW LIMIT.

FIGURE (1-5) TEMPERATURE SAFETY LIMITS

1-7. SPECIFICATIONS OF THE BLANKETROL II UNIT

BLANKETROL II MODEL 222R FEATURES

PHYSICAL

Dimensions: 17"W x 17"D x 36"H (43.18cm.W x 43.18 cm.D x 91.44cm.H)

Weight: 134 lbs. (60.3kg.)

Cabinet Construction:

Epoxy-coated steel with plastic top. Dual reservoir. Bottom air discharge. Molded-in handle. Bumper guard. Storage compartment. Four 5" conductive, 360° swivel-type casters.

CONTROL SYSTEM

Microprocessor controlled, Lighted "ON-OFF" switch, °C or °F Switch, Digital LED Read Outs, 6 Alarm Indications, 4 Mode Indications.

Controller Range:

Water Temp.:	4°C to 42°C (39.2°F to 107.6°F)
Patient Temp.:	30°C to 40°C (86°F to 104°F)

Display Accuracy:

Water Temp.	± .5°C (± 1°F)
Patient Temp.	± .25°C (± .5°F)

Display Range:

Water Temp.	0°C - 50°C (32°F - 122°F)
Patient Temp.	10°C - 43.5°C 50°F - 110°F

Display Type: Digital/Color-Coded

Temp.Settings:

Water Temp.:	.1°C (.2°F)
Patient Temp.:	.1°C (.2°F)

Patient Probe Jacks: One

Probe Type: YSI Series 400

THERMAL SYSTEM

Compressor: 1/3 HP (Copeland)

Heater: 800 Watts

NOTE: Water cooling rate is approximately 4°C (8°F) per minute and the heating rate is approximately 3°C (6°F) per minute.

CIRCULATING SYSTEM

Dual Reservoirs, 2 gallon (7½ liters) total capacity. Error proof, quick-disconnect couplings. All circulating components are non-corrosive.

ELECTRICAL SYSTEM

Electrical Characteristics:

(Std.) 115V,60Hz., 9.6 Amps
(Opt.) 220V,50Hz., 5 Amps

Power Cord: 16/3 SJT, Hospital grade plug

Leakage Current: Under 100 μa

Circuit Breaker: In Power Switch

SAFETY SYSTEM

Maximum High Control Setting:
42°C (107.6°F)

Primary High:
44.6°C ± 1°C (112°F ± 2°F)

Secondary High Independent Backup:
46°C ± 2°C (115°F ± 4°F)

Maximum Low Control Setting:
4°C (39.2°F)

Primary Low:
3°C ± 1°C (37°F ± 2°)F

Secondary Low Independent Backup:
1°C ± .5°C (34°F ± 1°F)

1-7. SPECIFICATIONS OF THE BLANKETROL II UNIT (cont'd)

BLANKETROL II MODEL 222R FEATURES

Defective or Dislodged Probe Alarm:
Audible & Visual

Primary & Secondary High and Secondary Low Limit Failure Alarm:
Audible & Visual

Low Water Alarm: Audible & Visual

Defective Water Temp Sensor:
Audible & Visual

Water Flow Indicator: Visual
Optional: Low Flow Alarm Kit
Audible & Visual

WARRANTY

2 yr. parts (compressor-additional 3 years pro-rated)

SECTION 2. GENERAL PREPARATION OF THE BLANKETROL II SYSTEM

2-1. INTRODUCTION

This section describes the procedures to prepare the BLANKETROL II unit for general use. This entails unpacking the shipment, arranging all the equipment the first time, and completing a test routine. This section also outlines the optional distilled/sterile water-bacteriocidal agent preparations, standard safety precautions, and patient preparation/bedside care when using the hyper-hypothermia blanket(s).

2-2. UNPACKING THE SHIPMENT

Inside the packing carton, the BLANKETROL II unit is covered with a plastic wrap and is cushioned with foam padding on the top. Corrugated cardboard protectors on the top, bottom, and four corners. A large envelope with the manuals, warranty card, and the drain hose is enclosed in the storage compartment of the unit. BE SURE TO COMPLETE AND RETURN THE WARRANTY CARD.

During the unpacking process, look carefully for signs of shipping damage. If any damage is found, notify the transportation company immediately and file a claim. The transportation company is responsible for the shipment after it leaves the factory. If problems other than shipping damage are found, notify your Cincinnati Sub-Zero representative or the Cincinnati Sub-Zero office at 1-800-989-7373.

2-3. FIRST TIME SET-UP/SYSTEM TEST ROUTINE

This section describes the tasks necessary to inspect and arrange the equipment for the first time after unpacking and describes a System Test Routine to check out the control panel.

The System Test Routine can also be used to teach operators unfamiliar with the equipment how to use the unit.

The following tasks should be completed prior to assigning the unit for floor use:

2-3.1. INSPECTING AND ARRANGING THE EQUIPMENT

a. Place the BLANKETROL II unit in an uncluttered work space that is accessible to the correct power source. Position the unit so that the control panel faces the operator.

2-3.1. INSPECTING AND ARRANGING THE EQUIPMENT (cont'd)

b. If the unit was shipped on its side, permit the unit to rest in an upright position for approximately one hour before operating.

c. Review Section (1-4.) to identify the features of the BLANKETROL II unit.

d. Collect and arrange the following equipment and supplies:

1. Hyper-hypothermia blanket(s) described in Section (1-5.)
2. Connecting hose with quick-disconnect fittings if using disposable blanket(s)
3. Distilled/sterile water or the distilled/sterile water-bacteriocidal preparation described in Section (2-4.). DO NOT USE ALCOHOL or DE-IONIZED WATER. The reservoir holds approximately 2 gallons (7½ liters). Each empty blanket that is connected to the unit requires approximately ½ gallon (1.9 liters) of water.

e. Visually inspect the BLANKETROL II unit to determine that there are no missing parts, unusual dents or punctures.

f. Examine the power cord for cuts or exposed wires and the power plug (3-prong for 115/100 VAC units, appropriate plug for 220/240 VAC units) for bent or missing prongs.

g. Lift the lid of the water fill opening and gradually pour approximately 2 gallons (7½ liters) of distilled/sterile water or the distilled/sterile water-bacteriostatic agent preparation into the reservoir. Stop pouring when the water reaches the strainer visible at the bottom of the water fill opening.

h. Connect the blanket(s) to the BLANKETROL II unit by attaching the quick-disconnect female coupling of the connecting hose to a male outlet coupling (on the bottom row) of the unit. Attach the male quick-disconnect coupling of the connecting hose to a female return coupling (on the top row) of the unit. Each blanket must be connected to one outlet and one return.

2-3.1. INSPECTING AND ARRANGING THE EQUIPMENT (cont'd)

To attach the couplings:

1. Grasp the female coupling of the connecting hose
2. Slide the collar back towards the hose
3. Push the female coupling over a male coupling of the unit
4. Allow the collar to SNAP into place and return to its original position
5. Gently pull on the connecting hose to assure a positive connection
6. Next, push back the collar of a female return hose on the unit with one hand
7. With the other hand, insert the male coupling of the connecting hose
8. Release the collar of the female return coupling
9. Push the male coupling until it SNAPS into position
10. Gently pull the connecting hose to assure a positive connection

i. Check that the blanket is laying flat and that the connecting hose to the unit is not twisted or pinched.

j. Check that the power switch of the unit is OFF.

k. Insert the 3-prong plug for 115/100 VAC units (appropriate ground plug for 220/240 VAC units) into a properly grounded hospital grade receptacle.

WARNING: DO NOT BY-PASS THE GROUND PLUG. ELECTRICAL HAZARDS MAY RESULT.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE

After arranging the equipment as described in Section (2-3.1.), complete this System Test Routine which describes what switches to press and the changes to observe.

a. Make sure that the power switch is in the "ON" position.

1. The switch lights up green.
2. The microprocessor board goes through self-test.
3. The status display in the center of the control panel flashes CK SETPT.
4. The Celsius or Fahrenheit indicator lights up.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE (cont'd)

If any of the above are not observed, consult the Troubleshooting Guide in Section (6.) of the Operation/Technical Manual. If they are observed, continue with the test routine.

b. Press and hold the TEST INDICATOR switch.

1. The yellow and green arrow, the LED's in the corner of the switches, the Celsius/Fahrenheit indicator, and the Remove From Service indicator flash on and then off.
2. Then, all the displays flash.

The operator should note that all the displays and indicators do light up. If they do not light up, consult the Troubleshooting Guide in Section (6.) of the Operation/Technical Manual. If they do light up, continue with the test routine. The Status display continues to flash CK SETPT.

c. Press the TEMP SET switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The Status display shows SET TEMP.
4. The Setpoint display shows 37°C or 98.6°F (depending upon the position of the Celsius/Fahrenheit indicator switch). Each time the operator presses the TEMP SET switch after just having plugged in the unit, the Setpoint display shows 37°C or 98.6°F.

d. Change the position of the Celsius/Fahrenheit Selector switch (on the front of the unit).

1. The Setpoint display changes from 37°C to 98.6°F (or from 98.6°F to 37°C).
2. The Celsius/Fahrenheit indicator changes from Celsius to Fahrenheit (or from Fahrenheit to Celsius).

e. Press the MONITOR ONLY switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. Celsius/Fahrenheit indicator is lit.
4. The Status display shows MONITOR.
5. The Setpoint display is blank.
6. For this test routine, the Patient display is blank because the probe is not inserted in the probe jack.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE (cont'd)

f. Press the TEMP SET switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The Celsius/Fahrenheit indicator is lit.
4. The Setpoint display shows 37°C or 98.6°F.
5. The Status display shows SET TEMP.

NOTE: **IN ORDER TO CHANGE FROM ONE MODE TO ANOTHER, THE TEMP SET SWITCH MUST BE PRESSED BEFORE THE NEXT MODE CAN BE SET.** For example; to change from Monitor Only Mode to Manual Control Mode, the Temp Set switch must be pressed first before the Manual Control Mode switch can be pressed.

g. Press the MANUAL CONTROL switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The Celsius/Fahrenheit indicator is lit.
4. The Setpoint display shows a temperature reading.
5. The Blanket/Water display shows the temperature of the water in the reservoir.
6. The green arrow (left of the Setpoint display) lights up.
7. The Status display shows COOLING, AT SETPT or HEATING, depending upon the relationship of the water in the reservoir to the Setpoint.
8. A LED corresponding to the Status display lights up green for COOLING, yellow for AT SETPT, or red for HEATING.
9. The pump is activated; there is a soft hum.
10. The heater or compressor may be activated.
11. The Water Flow indicator on the right side panel begins to move. The water moves from the unit through the blanket and returns to the unit.

If in the process of filling the blankets the water is no longer visible in the bottom of the water fill opening, more distilled/sterile water should be added.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE (cont'd)

If at any time the water falls below a preset limit, the Low Water sensor is activated and the Status display flashes LO WATER and the alarm sounds. The unit shuts down and the operator cannot proceed until this is corrected as described in Section (3-8.).

h. Check the blanket for leaks. If a leak is found, the blanket cannot be used. The repair of reusable blankets is described in Sec (4-6) of the Operation/Technical Manual.

i. Check the couplings at the unit and at the blanket for positive connection.

j. Press the TEMP SET switch
   1. The microprocessor board beeps.
   2. The LED in the corner of the switch lights up.
   3. The green arrow left of the Setpoint display goes out.
   4. The Blanket/Water display goes blank.
   5. The Celsius/Fahrenheit indicator is lit.
   6. The Status display shows SET TEMP.
   7. The pump shuts down, the heating/cooling stops.

   When the TEMP SET switch is pressed, the operating mode (e.g. Manual Control Mode, Automatic Control Mode or Monitor Only Mode) is cancelled. The operator is once again at the beginning of the mode selection procedure.

k. Press the Up arrow next to the TEMP SET switch.

   1. The microprocessor board beeps each time it is pressed.
   2. The Setpoint display changes; the numbers move up the scale. The longer the switch is pressed the faster the digits change. When the switch is released and repressed, the digits once again change slowly and then increase in speed. The highest setting is 42°C or 107.6°F.

l. Press the Down arrow next to the TEMP SET switch.

   1. The microprocessor board beeps each time it is pressed.
   2. The Setpoint display changes; the numbers move down the scale. The longer the switch is pressed the faster the digits change. When the switch is released and repressed, the digits once again change slowly and then increase in speed. The lowest setting is 4°C or 39.2°F.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE (cont'd)

m. Press the Up arrow or Down arrow so that the SETPOINT display shows a number between 30°C - 40°C (86°F - 104°F). For example, set the display to show 32.3°C or 90°F.

n. Insert a YSI 400 series probe jack on the side of the unit.

o. Press the AUTO CONTROL switch.

1. The Setpoint display goes blank.
2. The alarm sounds.
3. The Status display flashes CK PROBE.

The alarm sounds because the patient probe, as held by the operator in the open air, for this test routine, detects a reading below 30°C (86°F). The unit will not operate in the Auto Control Mode unless the probe is properly placed on a patient and reading above 30°C (86°F).

p. Press the SILENCE ALARM switch.

1. The alarm stops.
2. The Status display continues to flash CK PROBE.

The Operator has 5 minutes to correct the problem. In an actual situation, the operator would check the probe and then continue operation.

q. Press the TEMP SET switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The Setpoint display shows a temperature reading.
4. The Status display shows SET TEMP.

r. Press the Up arrow or the Down arrow so that the Setpoint display shows a number less than 30°C (86°F) or greater than 40°C (104°F). For example, set the display to show 41°C or 106°F.

s. Press the AUTO CONTROL switch.

1. The Setpoint display goes blank.
2. The Status display flashes CK SETPT.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE (cont'd)

The display flashes because the Setpoint temperature is outside the Automatic Control Mode temperature range of 30°C-40°C (86°F-104°F). The unit will not operate in Automatic Control Mode unless the Setpoint display shows a number within the range.

t. Press the TEMP SET switch

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The Setpoint display shows a temperature reading.
4. The Status display shows SET TEMP.

u. Press the MANUAL CONTROL switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The green arrow left of the Setpoint display lights up.
4. The Celsius/Fahrenheit indicator is lit.
5. The Blanket/Water display shows the temperature of the water in the reservoir.
6. The Patient display shows the temperature reading of the probe, as it is held by the operator, if the probe reading is in the range of 10°C -43.5°C (50°F - 110°F).
7. The Setpoint display shows a temperature reading.
8. The Status display shows COOLING, AT SETPT, or HEATING depending upon the relationship of the water in the reservoir to the Setpoint.
9. A LED corresponding to the Status display lights up: green for COOLING, yellow for AT SETPT, or red for HEATING.
10. The pump is activated; there is a soft hum.
11. The heater or compressor may be activated.
12. The water flow indicator on the right side panel begins to move.

This step is included to show that the patient display lights up when the probe is inserted and the unit is in the Manual Control Mode as well as when the unit operates in the Automatic Control Mode.

v. To complete this test routine, turn the power switch OFF.

1. The control panel goes blank.
2. The green light of the power switch goes out.

2-3.2. COMPLETING A SYSTEM TEST ROUTINE (cont'd)

If the power switch is set ON again without having unplugged the unit and the Temp Set switch is pressed, the Setpoint display shows the temperature that was on the display prior to the operator turning the unit off.

w. Remove the probe from the probe jack, loosely coil it and place it in the storage drawer in front of the unit. In an actual situation, the probe is cleaned as described in Section (4-7.) of the Operation/Technical Manual before it is stored.

x. Disconnect the power cord from the power source, loosely coil it and attach it to the back panel using the nylon strap.

y. For reusable - PLASTIPAD - blankets, disconnect the connecting hose from the unit. Loosely coil the hose lengthwise in the center of the blanket. Fold the blanket lengthwise into the center, 1/3 from the left side and 1/3 from the right side. The water can remain in the blanket and in the unit between periods of use.

For single-use MAXI-THERM blankets, follow the instructions packaged with the blanket. The water should be changed monthly as described in Section (4-2.) of the Operation/Technical Manual.

The BLANKETROL II System; unit, connecting hose, blanket(s), and probe are now ready for patient use.

2-4. SUGGESTIONS FOR PROTECTING THE RESERVOIR FROM BACTERIA AND FOR DECONTAMINATION GUIDELINES

If distilled/sterile water is used and changed monthly, there should be no problem with bacteria forming in the reservoir or blanket(s). If hospital procedures require the use of a bacteriostatic or bactericidal agent, we suggest Hospital-Approved Bacteriocidal Agents which are non-acidic and non-foaming.

NOTE: DO NOT USE DE-IONIZED WATER. THE MAJORITY OF DE-IONIZERS DO NOT MAINTAIN A NEUTRAL PH OF 7. IF THE DE-IONIZED WATER IS ACIDIC, IT WILL CAUSE A BATTERY EFFECT AND THE COPPER REFRIGERATION LINE WILL BEGIN TO DETERIORATE AND CAUSE A LEAK IN THE REFRIGERATION SYSTEM.

2-4. SUGGESTIONS FOR PROTECTING THE RESERVOIR FROM BACTERIA AND FOR DECONTAMINATION GUIDELINES

SUGGESTED DECONTAMINATION GUIDELINES FOR CINCINNATI SUB-ZERO EQUIPMENT

(Developed in conjunction with the risk management department at the Shriners Burn Institute in Cincinnati, Ohio)

Decontamination in the Healthcare environment is of the utmost concern with today's array of potential infectious diseases. Cincinnati Sub-Zero has always been aware of these concerns in conjunction with the water reservoirs and circulatory systems of CSZ equipment. For this reason, all CSZ equipment have a suggested monthly schedule for flushing and cleaning the water system in an effort to inhibit the growth of bacteria and fungi.

The following decontamination procedure was developed to effectively rid the water system of all bacteria and not damage any of the internal components of the equipment. All Steps should be followed as closely as possible. This decontamination procedure should be conducted every three (3) months.

The Procedure:

a. Drain the water from the reservoir as described in Section (4-2.1).

b. Flush the unit three (3) times per the following procedure.
   1. Add one (1) ounce (30 cc) of household bleach (sodium hypochlorite) to the empty water reservoir.

CAUTION:	**IT IS STRONGLY SUGGESTED THAT APPROPRIATE EYE PROTECTION AND GLOVES BE WORN WHEN HANDLING AND USING BLEACH. WEARING AN APRON IS ALSO SUGGESTED TO PROTECT CLOTHING.**

   2. Fill the reservoir with warm tap water.

   3. Turn the unit on and circulate per the chart below.

2-4. SUGGESTIONS FOR PROTECTING THE RESERVOIR FROM BACTERIA AND FOR DECONTAMINATION GUIDELINES (cont'd)

UNIT	MODE	TEMPERATURE	DURATION
Blanketrol II	Manual	100°F	5 Min.

4. Drain the unit after each flush.

c. Rinse the unit three (3) times as described in (b) except to omit the household bleach (sodium hypochlorite).

d. After the third rinse, drain the unit and add 32 ounces (1 liter) of sterile distilled water to the water reservoir and circulate.

e. Check the water with "Fac-Chek" Ph strips or other appropriate test method for detecting bleach. If bleach is detected, repeat steps (c,d,e).

f. Once no bleach is detected, add the appropriate amount of U.S.P. Grade Propylene Glycol to the water reservoir per the following chart:

UNIT	U.S.P. GRADE PROPYLENE GLYCOL PER UNIT
Blanketrol II	16 oz. (500 cc)

g. Continue to fill the water reservoir with sterile distilled water.

h. Document the maintenance of the unit.

i. The unit is now ready to be placed back in service.

2-5. UNIT AND PATIENT RELATED PRECAUTIONS

This unit requires both water and electricity to operate.

WARNING: ANYTIME WATER IS FOUND LEAKING INTO OR AROUND THE UNIT, THE CONNECTING HOSE, AND/OR BLANKET, TURN THE UNIT OFF, DISCONNECT THE POWER CORD FROM ITS POWER SOURCE, AND CORRECT THE PROBLEM BEFORE PROCEEDING.

CAUTION: EXERCISE EXTREME CAUTION IF THE UNIT IS USED FOR PATIENTS WHO ARE ELECTRICALLY SUSCEPTIBLE (PROBE, CATHETER, OR ELECTRODES DIRECTLY CONNECTED TO THE HEART).

1. Test for leakage current prior to general floor use. See Section (5-18.) of the Operation/Technical Manual.

2. Anytime a repair is made, make sure that the power cord is disconnected from the power source before disassembly.

3. The repair and servicing of the BLANKETROL II unit as described in Section (5.). requires no special tools. However, only persons with the proper skills and knowledge should undertake any repairs, servicing or maintenance of the unit.

4. The high and low temperature safety devices protect the patient and the unit from injury or damage that can be caused by temperature extremes. At the same time, a patient should be monitored closely when hyper-hypothermia treatment is used.

5. Anytime the unit sounds an alarm, the operator should immediately check the Status display and act accordingly, e.g., add water, remove from service, check the probe.

6. The BLANKETROL II unit is equipped with a circuit breaker in the ON/OFF power switch to protect against current overload.

2-6. PATIENT PREPARATION AND BEDSIDE CARE

Effective use of the BLANKETROL II system must include proper patient care prior to and while using the hyper-hypothermia blanket(s). Standard nursing procedures, before using the blanket(s), include the following tasks:

CAUTION: THE DESIRED SETPOINT TEMPERATURE SHOULD BE SET ONLY AS PRESCRIBED AND UNDER THE ORDER OF A PHYSICIAN.

a. A base line recording should be made of vital signs, level of consciousness and responsiveness.

b. Lanolin or a lanolin/cold-cream mixture may be applied to the patient's exposed skin.

c. Protective wraps may be used to cover patient's hands and feet.

d. As ordered, a retention urinary catheter may be inserted to evaluate renal function and renal output.

e. As ordered, an intravenous infusion may be started.

f. As ordered, preinduction medications may be administered.

g. A dry sheet or DISPOSA-COVER should be placed between the hyper-hypothermia blanket and the patient.

Standard nursing procedures while using a hyper-hypothermia blanket include the following tasks:

a. Patient's vital signs should be recorded and evaluated frequently. Operating room, temperature sensitive and pediatric patients may deviate from normal responses to external applications of heat and cold. Patient core temperature and the condition of the skin in contact with the blanket and blanket water temperature should be checked every twenty minutes. Operating room, temperature sensitive and pediatric patients should be checked more frequently. Notify the physician if the patient's core temperature does not reach the prescribed temperature in the time prescribed or deviates from the prescribed temperature range.

2-6. PATIENT PREPARATION AND BEDSIDE CARE (cont'd)

b. The position and the placement of the probe should be inspected regularly. Also, the BLANKETROL II unit activates an alarm when the patient probe registers outside the range of 30°C - 43.5°C (86°F - 110°F).

c. Level of consciousness, strength of extremities, changes in cardiac rate, changes in cardiac rhythms, pupil size, and response should be observed and recorded.

d. Changes in skin color, edema, inflammation, or indications of pressure, especially over bony prominences, should be noted and treated as ordered. Prevent prolonged tissue pressure and shearing forces over bony prominences.

e. The patient should be turned and properly positioned frequently.

f. As ordered, medications to prevent shivering may be administered.

g. The patient's nasal passages, air-way and oral cavity should be kept free of secretions and/or mucus build-up.

WARNING: THE PATIENT SHOULD BE CONSTANTLY ATTENDED. THE MISUSE OF HYPER-HYPOTHERMIA EQUIPMENT PRESENTS THE POTENTIAL FOR PATIENT INJURY.

CAUTION: THE APPLICATION OF HEATING OR COOLING MAY EFFECT THE TOXICITY OF SOLUTION. PREP SOLUTIONS HAVE BEEN REPORTED TO INJURE THE SKIN WHEN ALLOWED TO REMAIN BETWEEN PATIENT AND A WATER-CIRCULATING HEATING BLANKET DURING PROLONGED PROCEDURES. -- **KEEP THE AREA BETWEEN THE PATIENT AND THE BLANKET DRY.**

SECTION 3 OPERATING THE BLANKETROL II SYSTEM

3-1. INTRODUCTION

This section describes how to operate the BLANKETROL II unit in order to control your patient's temperature. First, collect the equipment and prepare the patient. Second, decide which mode of operation to use. Third, set the appropriate controls; Automatic Control Mode, Manual Control Mode, or Monitor Only Mode.

3-2. ARRANGING THE SYSTEM COMPONENTS

a. Collect all supplies and equipment.

1. BLANKETROL II unit
2. Hyper-hypothermia blanket(s)
3. Dry sheet, bath blanket or DISPOSA-COVER
4. Connecting hose, if using MAXI-THERM disposable blanket(s)
5. YSI 400 series probe
6. Connector cable (if using disposable probes)
7. Distilled/sterile water

b. Place the BLANKETROL II unit in the patient area, accessible to the correct power source.

c. Review Section (1-4.) that outlines the features of the unit and control panel.

d. Check the level of distilled/sterile water in the reservoir. To do so, lift the cover of the water fill opening and the water should be visible, touching the strainer. If needed, carefully add distilled/sterile water. In addition, if the water falls below a preset level, the alarm sounds and the Status display flashes LO WATER. The operator cannot proceed until this is corrected as described in Section (3-8.).

e. Check that the power switch is in the OFF position.

f. Inspect the power plug (3-prong for 115/100 VAC units, appropriate plug for 220/240 VAC units) for bent or missing prongs.

g. Insert the 3-prong plug for 115/100 VAC (appropriate ground plug for 220/240 VAC units) into a properly grounded hospital grade receptacle.

3-2. ARRANGING THE SYSTEM COMPONENTS (cont'd)

WARNING: DO NOT BY-PASS THE GROUND PLUG; ELECTRICAL HAZARDS MAY RESULT.

h. Lay the hyper-hypothermia blanket flat with the hose arranged without kinks towards the unit.

i. If the blanket is already filled, check that there are no leaks.

j. Cover the blanket with a dry sheet, bath blanket or DISPOSA-COVER.

k. Connect the blanket to the BLANKETROL II unit as described in Section (2-3.1.), Step (h).

l. If a MAXI-THERM single-patient use hyper-hypothermia blanket is used, connect the color coded couplings of the connecting hose to the blanket as described in the instructions packaged with each blanket.

m. Check that the blanket is flat and the connecting hose is not twisted or pinched.

n. The hyper-hypothermia blanket may be precooled or prewarmed before positioning the patient. To do so, operate the unit in Manual Control Mode for a few minutes.

o. Place the patient on the hyper-hypothermia blanket.

p. If the patient's temperature is to be monitored as required in Automatic Control Mode or Monitor Only Mode, insert into or attach to the patient a YSI 400 Series probe.

1. A rectal probe is inserted into the rectum and secured with tape to the leg of the patient.

2. The diaphragm of a skin probe is taped to the patient, usually under the patient's arm or on the chest.

3. The esophageal probe is inserted into the patient. It is often preferred that the patient is comatose or under anesthesia.

   The probe should be inspected periodically to insure that it is not dislodged or impacted. The BLANKETROL II unit sounds an alarm when the reading from the probe falls below 30°C (86°F). It is

3-2 ARRANGING THE SYSTEM COMPONENTS (cont'd)

important that the probe be inserted into or attached to the patient at least one minute before pressing a Control Mode switch. This will prevent the accidental triggering of the CK PROBE Status message.

q. If a hyper-hypothermia blanket is to be used on top of the patient, cover it with a DISPOSA-COVER or place a sheet between the patient and the thermal blanket.

r. Connect the blanket on top of the patient to the BLANKETROL II unit following the procedure described in Section (2-3.1.) Step (h).

s. If a hyper-hypothermia blanket is not used on top of the paitent, cover the patient with a top sheet and/or blanket. Patient preparation and bedside care are further described in Section (2-6.).

t. Choose which operating mode to use: Operating in Automatic Control Mode is described in Section (3-3.). Operating in Manual Control Mode is described in Section (3-4.). Operating in Monitor Only Mode is described in Section (3-6.).

3-3. OPERATING THE BLANKETROL II UNIT IN AUTOMATIC CONTROL MODE

The BLANKETROL II unit can be set so that it operates based upon the actual temperature of the patient relative to the SETPOINT temperature. To do so, set the desired patient temperature in Celsius or Fahrenheit, insert into or attach to the patient a probe and press the AUTO CONTROL switch. The BLANKETROL II unit activates to heat or cool the water, to circulate the water, and to control and monitor the change in the patient's temperature.

After arranging the equipment as described in Section (3-2.), proceed as follows:

a. Check the placement of the YSI 400 series probe in or on the patient.

b. Insert the probe plug into the probe jack on the right side of the unit.

c. Press the power switch ON
   1. The switch lights up green.
   2. The microprocessor board goes through self test.
   3. The Status display flashes CK SETPT.
   4. The Celsius or Fahrenheit indicator lights up.

3-3. OPERATING THE BLANKETROL II UNIT IN AUTOMATIC CONTROL MODE (cont'd)

d. Consult the physician's orders to determine the desired patient temperature. As a safety precaution, the SETPOINT display can only be set between 30°C - 40°C (86°F - 104°F) to operate in Automatic Control Mode.

e. Set the Celsius/Fahrenheit Selector switch (on the front panel) so that the required indicator (Celsius or Fahrenheit) is showing on the control panel.

f. Press the TEMP SET switch

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The SETPOINT display shows a temperature reading.
4. The Status display shows SET TEMP.

g. Press the Up arrow or Down arrow to change the SETPOINT display to the desired patient temperature. The display can only be set between 30°C -40°C (86°F - 104°F).

1. The microprocessor board beeps.
2. The SETPOINT display changes.

h. Press the AUTO CONTROL switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The yellow arrow to the right of the SETPOINT display lights up.
4. The Patient display shows the patient's actual temperature.
5. The Blanket/Water display shows the actual temperature of the circulating water.
6. The Status display shows COOLING, AT SETPT, or HEATING depending upon the relationship of the patient's temperature to the SETPOINT display.
7. A LED corresponding to the Status display lights up: green for COOLING, yellow for AT SETPT, or red for HEATING.
8. The pump is activated. There is a soft hum. The heater or compressor may also be activated.
9. The Water Flow indicator on the right side panel begins to move.
10. The water moves from the unit to the blanket and returns to the unit.

3-3. OPERATING THE BLANKETROL II UNIT IN AUTOMATIC CONTROL MODE (cont'd)

i. Check the Water Flow indicator to confirm that the water is circulating.

j. Feel the hyper-hypothermia blanket to confirm that the blanket is heating/cooling.

k. To make any changes in the control settings, press the TEMP SET switch and begin again.

The BLANKETROL II Unit is now operating in Automatic Control Mode. You should continue to monitor the unit and the patient. (Review the suggestions for patient care described in Section (2-6.).

If at any time the Status display shows a message other than the messages described in Automatic Control Mode procedures, make the changes indicated by the display and/or consult the list of display messages in Section (3-8.). At any time the unit sounds an alarm and the Status display flashes a message, make the changes indicated.

To turn off the unit or discontinue hyper-hypothermia treatment, proceed as described in Section (3-7.).

NOTE: IN ORDER TO CHANGE FROM AUTOMATIC CONTROL MODE TO MANUAL CONTROL MODE, FIRST PRESS THE TEMP SET SWITCH AND THEN PROCEED TO MANUAL CONTROL MODE.

In order to change from Automatic Control Mode to Monitor Only Mode, simply press the Monitor Only switch.

WARNING: IF AT ALL POSSIBLE, REMOVE THE PROBE FROM PATIENT CONTACT BEFORE ACTIVATING AN ELECTROSURGICAL UNIT. THE RF INTERFERENCE MAY CAUSE THE PATIENT TEMPERATURE TO JUMP UP AND DOWN AND CYCLE THE MACHINE FROM COOLING TO HEATING OR VICE VERSA.

3-4. OPERATING THE BLANKETROL II UNIT IN MANUAL CONTROL MODE

The BLANKETROL II unit can be set so that it operates based upon the actual temperature of the circulating water relative to the SETPOINT temperature. To do so, set the desired water temperature, in Celsius or Fahrenheit, and depress the MANUAL CONTROL Switch. The BLANKETROL II unit activates to heat or cool the water and to circulate the water. The operator must continue to monitor the patient's temperature.

Given the many variables such as patient size, weight, or condition, there is no direct relationship between the temperature of the circulating water and the patient's temperature. Both water temperature and the patient temperature should be closely monitored.

After arranging the equipment as described in Section (3-2.), proceed as follows:

a. Press the power switch ON.

   1. The switch lights up green.
   2. The microprocessor board goes through self-test.
   3. The Status display flashes CK SETPT.
   4. The Celsius or Fahrenheit indictor lights up.

b. Consult the physician's orders to determine the desired patient temperature and the desired water temperature setting.

c. Set the Celsius/Fahrenheit Selector switch (on the front panel) so the required indicator (Celsius or Fahrenheit) is showing on the control panel.

d. Press the TEMP SET switch.

   I. The microprocessor board beeps.
   2. The LED in the corner of the switch lights up.
   3. The SETPOINT display shows a temperature reading.
   4. The Status display shows SET TEMP.

e. Press the Up arrow or Down arrow to change the SETPOINT display to the desired Blanket/Water temperature. As a safety precaution, the Blanket/Water temperature can only be set between 4°C - 42°C (39.2°F - 107.6°F).

3-4. OPERATING THE BLANKETROL II UNIT IN MANUAL CONTROL MODE (cont'd)

1. The microprocessor board beeps.
2. The SETPOINT display changes.

f. Press the MANUAL CONTROL switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The green arrow to the left of the SETPOINT display lights up.
4. The BLANKET/WATER display shows the actual temperature of the circulating water.
5. The Status display shows COOLING, AT SETPT, or HEATING depending upon the relationship of the circulating water to the SETPOINT display.
6. A LED corresponding to the Status display lights up: green for COOLING, yellow for AT SETPT, or red for HEATING.
7. The pump is activated. There is a soft hum. The heater or compressor may be activated.
8. The Water Flow indicator on the right side panel begins to move.
9. The water moves from the unit through the blanket and returns to the unit.

g. Check the Water Flow indicator to confirm that the water is circulating.

h. Touch the hyper-hypothermia blanket to confirm that the blanket is heating/cooling.

i. To make any changes in the control setting, press the TEMP SET switch and begin again.

The BLANKETROL II unit is now operating in Manual Control Mode. The operator must continue to monitor the change in the patient's temperature. (Review the suggestions for patient care described in Section (2-6.).

When operating in Manual Control Mode, the unit should be turned off when the patient's temperature is .5°-1°C (1°-2°F) above the desired patient temperature to avoid complications associated with temperature drift and after fall.

If at any time the Status display shows a message other than the messages described in Manual Control procedures, make the changes indicated by the display and/or consult the list of display messages in Section (3-8.). At any time the unit sounds an alarm and the Status display flashes a message, make the changes as indicated.

3-4. OPERATING THE BLANKETROL II UNIT IN MANUAL CONTROL MODE (cont'd)

To turn off the unit or discontinue hyper-hypothermia treatment, proceed as described in Section (3-7.).

NOTE:	IN ORDER TO CHANGE FROM A MANUAL CONTROL MODE TO AUTOMATIC CONTROL MODE, FIRST PRESS THE TEMP SET SWITCH AND THEN PROCEED TO AUTOMATIC CONTROL MODE.

In order to change from Manual Control Mode to Monitor Only Mode, simply press the Monitor Only switch.

3-5. OPERATING THE BLANKETROL II UNIT IN MANUAL CONTROL MODE WITH THE ADDITION OF THE PATIENT PROBE

When the BLANKETROL II Unit is set to operate in Manual Control Mode, the patient probe can be inserted to monitor the patient's temperature. The unit continues to operate based upon the temperature of the circulating water relative to the desired Blanket/Water temperature.

After arranging the equipment as described in Section (3-2.), proceed as follows:

a. Check the placement of the YSI 400 series probe in or on the patient.

b. Insert the probe plug into the probe jack on the right side of the unit.

c. Follow Steps (a - i) as described in Section (3-4.). In addition to the Blanket/Water display showing actual water temperature, the Patient display shows the actual patient temperature.

The BLANKETROL II Unit is now operating in Manual Control Mode while monitoring the patient's temperature. However, you must also monitor the patient's temperature. (Review the suggestions for patient care described in Section (2-6.).

When operating in Manual Control Mode, the unit should be turned off when the patient's temperature is .5° - 1°C (1°-2°F) above the desired patient temperature to avoid complications associated with temperature drift and after fall.

If at any time the Status display shows a message other than the messages described in Manual Control procedures, make the changes indicated by the display and/or consult the list of display messages in Section (3-8.). At any time the unit sounds an alarm and the Status display flashes a message, make the changes as indicated.

3-5. OPERATING THE BLANKETROL II UNIT IN MANUAL CONTROL MODE WITH THE ADDITION OF THE PATIENT PROBE (cont'd)

To turn off the unit or discontinue hyper-hypothermia treatment, proceed as described in Section (3-7.).

NOTE: IN ORDER TO CHANGE FROM AUTOMATIC CONTROL MODE TO MANUAL CONTROL MODE, FIRST PRESS THE TEMP SET SWITCH AND THEN PROCEED TO MANUAL CONTROL MODE.

In order to change from Automatic Control Mode to Monitor Only Mode, simply press the Monitor Only switch.

WARNING: IF AT ALL POSSIBLE, REMOVE THE PROBE FROM PATIENT CONTACT BEFORE ACTIVATING AN ELECTROSURGICAL UNIT. THE RF INTERFERENCE MAY CAUSE THE PATIENT TEMPERATURE TO JUMP UP AND DOWN AND CYCLE THE MACHINE FROM COOLING TO HEATING OR VICE VERSA.

3-6. OPERATING THE BLANKETROL II UNIT IN MONITOR ONLY MODE

The BLANKETROL II unit can be set so it displays the patient's temperature but does not heat, cool, or circulate the water. In this operating mode the patient may or may not already be positioned on a hyper-hypothermia blanket, but the unit and the probe must be arranged as described in Section (3-2.).

After arranging the equipment, proceed as follows:

a. Check the placement of the YSI 400 series probe in or on the patient.

b. Insert the probe plug into the probe jack on the right side of the unit.

c. Press the power switch ON.

1. The switch lights up green.
2. The microprocessor board goes through self-test.
3. The Status display flashes CK SETPT.
4. The Celsius or Fahrenheit indicator lights up red.

3-6. OPERATING THE BLANKETROL II UNIT IN MONITOR ONLY MODE (cont'd)

d. Consult the physician's orders to determine the desired patient temperature.

e. Set the Celsius/Fahrenheit selector switch (on the front panel) so that the required indicator (Celsius or Fahrenheit) is showing on the control panel.

f. Press TEMP SET switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The SETPOINT display shows a temperature reading.
4. The Status display shows SET TEMP.

g. Press the MONITOR ONLY switch.

1. The microprocessor board beeps.
2. The LED in the corner of the switch lights up.
3. The Status display shows MONITOR.
4. The Patient display shows the patient's temperature.
5. The SETPOINT display goes blank.

h. To make any changes in the control settings, press the TEMP SET switch and begin again.

The BLANKETROL II unit is now operating in Monitor Only Mode.

If at any time the Status display shows a message other than the messages described in Monitor Only Mode procedures, make the changes indicated by the display and/or consult the list of display messages in Section (3-8.). If at any time the unit sounds an alarm and the Status display flashes a message, make the changes indicated. To turn off the unit or discontinue hyper-hypothermia treatment, proceed as described in Section (3-7.).

NOTE: IN ORDER TO CHANGE FROM MONITOR ONLY MODE TO ANOTHER OPERATING MODE, FIRST PRESS THE TEMP SET SWITCH AND THEN SET THE OPERATING MODE OF CHOICE.

3-6. OPERATING THE BLANKETROL II UNIT IN MONITOR ONLY MODE (cont'd)

WARNING: IF AT ALL POSSIBLE, REMOVE THE PROBE FROM PATIENT CONTACT BEFORE ACTIVATING AN ELECTROSURGICAL UNIT. THE RF INTERFERENCE MAY CAUSE THE PATIENT TEMPERATURE TO JUMP UP AND DOWN AND CYCLE THE MACHINE FROM COOLING TO HEATING OR VICE VERSA.

3-7. CONCLUDING HYPER-HYPOTHERMIA TREATMENT

After the patient temperature reaches the prescribed temperature for the prescribed amount of time, discontinue the use of the BLANKETROL II unit as ordered. Patient's temperature can drift up or down .5°C - 1°C (1°F - 2°F) after therapy has been discontinued. The drift may be greater if the patient has been shivering and treatment is abruptly discontinued. The operator should continue to monitor the patient's temperature. To do so, the operator may choose to operate the unit in Monitor Only Mode as described in Section (3-6.).

To change the mode of operation or to stop the unit, the operator must press the TEMP SET switch or turn the power switch OFF.

When the hyper-hypothermia therapy is concluded and the unit is turned OFF:

a. Permit the blanket(s) and hose to remain connected to the unit for about ten minutes. This allows some of the water to drain back into the unit.

b. Remove the probe from the patient and probe jack. Maintenance of the REUSABLE probe is described in Section (4-7.) of the Operation0/Technical Manual.

c. Disconnect the power cord from the power source, loosely coil it and attach it to the back panel using the nylon strap.

d. Disconnect the connecting hose from the unit.

e. Remove the blanket(s).

3-7. CONCLUDING HYPER-HYPOTHERMIA TREATMENT (cont'd)

f. For reusable PLASTIPAD blankets, loosely coil the hose lengthwise in the center of the blanket. Fold the blanket lengthwise into the center, 1/3 from the left side and 1/3 from the right side. Maintenance of the blanket is described in Section (4-6.) of the Operation/Technical Manual. For Single-Patient Use MAXI-THERM blankets, follow the instructions packaged with the blanket.

3-8. STATUS DISPLAY MESSAGES

The Status display located in the center of the BLANKETROL II unit control panel reports the operating status of the unit or indicates changes the operator must make. The Status display can show seventeen different messages to guide the operator. The following list defines each message and describes the changes, if any, the operator must make:

a. AT SETPT: This message occurs when the temperature of the circulating water (if in Manual Control Mode) or of the patient (if in Automatic Control Mode) is "AT SETPOINT" temperature.

b. COOLING: This message occurs when the temperature of the circulating water (if in Manual Control Mode) or of the patient (if in Automatic Control Mode) is above the SETPOINT temperature and the cooling system is activated.

c. HEATING: This message occurs when the temperature of the circulating water (if in Manual Control Mode) or of the patient (if in the Automatic Control Mode) is below the SETPOINT temperature and the heating system is activated.

d. CK SETPT: This message occurs when the operator should check the SETPOINT temperature for two possible reasons:

1. When the operator turns the unit ON after just having plugged in the unit, the flashing display indicates that the operator should check the SETPOINT temperature before proceeding. This is done by pressing the TEMP SET switch.

3-8. STATUS DISPLAY MESSAGES (cont'd)

2. When the operator presses the AUTO CONTROL switch, the CK SETPT message flashes if the SETPOINT display shows a temperature that is outside the temperature range of the Automatic Control Mode 30°C - 40°C (86°F - 104°F). The unit will not permit the operator to proceed to Automatic Control Mode operations until the SETPOINT is checked. To do so, the operator must press the TEMP SET switch and check/change the SETPOINT display. If the CK SETPT display flashes for five minutes, the alarm will sound until the operator proceeds to the next step. This alarm will also help to notify the operator if there has been an interruption in power.

e. CK PROBE: This message occurs when the operator must check the probe. This message flashes, the alarm sounds and the unit shuts down when the probe is sensing a temperature below 30°C (86°F). This can occur if the probe is not inserted in the probe jack prior to pressing the AUTO CONTROL switch, if the probe is dislodged from the patient, if the patient's temperature falls below 30°C (86°F), if the probe is defective, or if other than a YSI 400 Series probe was inserted into the probe jack. After pressing the blue SILENCE ALARM switch and checking the probe, the operator must press the TEMP SET switch to proceed.

f. HI TEMP: This message occurs when the water temperature reaches 44.6°C ± 1°C (112°F ± 2°F). The message flashes, the microprocessor board's beeper sounds and the heater shuts off. Pressing the silence alarm switch will silence the alarm for five minutes.

g. HI LIMIT: This message occurs when the back-up safety device is triggered because the circulating water and reservoir have reached the high temperature of 46°C ± 2°C (115°F ± 4°F). The message flashes, the alarm sounds, the unit shuts down and the REMOVE FROM SERVICE indicator lights up. The operator MUST disconnect the power cord from the power source; the alarm continues to sound until this is done. The unit cannot be used again until it is serviced as described in the Troubleshooting Guide, Section (6) of the Operation/Technical Manual.

3-8. STATUS DISPLAY MESSAGES (cont'd)

h. LO TEMP: This message occurs when the water temperature reaches 3°C ± 1°C (37°F ± 2°F) or more below the maximum low control setting. The message flashes and the microprocessor board's beeper sounds. The refrigeration solenoid closes. The operator MUST press the silence alarm switch or turn the unit off. The alarm continues to sound until this is done. The SILENCE ALARM switch will silence the alarm for one (1) minute. If the water temperature has risen more than 1°C (2°F) when the SILENCE ALARM switch is pressed, the unit will start operating normally.

i. LO LIMIT: This message occurs when the back-up safety device is triggered because the water temperature sensor has reached the low temperature limit of 1°C ± .5°C (34°F ± 1°F). The message flashes, the alarm sounds, the unit shuts down, and the REMOVE FROM SERVICE indicator lights up. The operator MUST unplug the unit; the alarm continues to sound until this is done. The unit cannot be used again until it is serviced as described in the Troubleshooting Guide, Section (6) of the Operation/Technical Manual.

j. LO WATER: This message occurs when the water in the reservoir is below a preset level. This message flashes, the alarm sounds and the unit shuts down until the water level is increased.

To do so, press the SILENCE ALARM switch and pour distilled/sterile water in the water fill opening until the water reaches the strainer visible at the bottom. The display changes to show Set Temp. In order to proceed, the operator must select an Operating Mode.

k. MONITOR: This message occurs when the unit is operating in the Monitor Only Mode. The unit does not heat, cool, or circulate water.

l. SENSOR: This message occurs when the water temperature sensor malfunctions. The message flashes, the alarm sounds, the unit shuts down, and the REMOVE FROM SERVICE indicator lights up. The operator MUST unplug the unit, the alarm continues to sound until this is done. The unit cannot be used again until it is serviced as described in Section (5-7.)of the Operation/Technical Manual.

m. SET TEMP: This message occurs when the TEMP SET switch is pressed. The SETPOINT display can now be changed by pressing the Up or Down arrow.

3-8. STATUS DISPLAY MESSAGES (cont'd)

n. BD PROBE: This message occurs if there is a direct short in the probe circuit. The message flashes, the alarm sounds and the unit shuts down only if the unit is operating in the Automatic control mode. When the unit is running in the Manual control mode or monitor only mode, the patient display will go blank if there is a direct short.

o. AD BAD: This message occurs if there is a problem in the analog to digital converter or affiliated circuitry. The unit's transformer (if defective) may also cause this message to appear.

p. NRAM BAD: This message occurs if there is a problem with the NOV RAM or affiliated circuitry.

q. CPU BAD: This message occurs if there is a problem with the Central Processing Unit or affiliated circuitry.

OPTIONAL:

The following messages will appear only on units with serial number 882-6870 and above equipped with a low flow alarm kit.

r. FLOW OK: This message occurs after positive flow is sensed returning to the unit. This message will display for thirty seconds after a positive flow is sensed.

NOTE:	IT IS NECESSARY TO HAVE A POSITIVE FLOW AND SEE THE "FLOW OK" MESSAGE BEFORE THE LOW FLOW ALARM WILL BE ACTIVATED.

s. LOW FLOW: This message occurs when the water flow is less than 6 GPH. The message flashes and the alarm sounds until the flow is increased above 6 GPH.

ACCESSORIES - BLANKETS

MAXI-THERM Single-Patient Use Blankets

276	Adult or O.R. Table Size (24" x 60")
274	Pediatric Size (22" x 30")
273	Infant Size (12" x 18")
	Contents: 5/box, 4 boxes/case
286	Reusable Connecting Hose (for CSZ Unit)
287	Reusable Connecting Hose (for Gaymar or American Unit)

PLASTIPAD Molded Plastic Blankets (Polyurethane)

196	Adult Size (24" x 60")
194	Pediatric Size (22" x 30")
193	Infant Size (12" x 18")
186	9' Blanket Extension Hose with Couplings
168	PLASTIPAD Patch Kit

DISPOSA-COVERS (Disposable Covers for H/H Blankets)

350	Adult Size - Bag Style (for CSZ No. 150)
351	Adult Size - Bag Style
351F	Adult Size - Fitted Style (for CSZ No. 151)
354	Pediatric Size - Bag Style
356	Adult Size - Bag Style

TEMPERATURE PROBES

YSI Reusable Probes

401	YSI Adult (Esophageal or Rectal)
402	YSI Infant (Esophageal or Rectal)
408	YSI (Banjo - Surface Temperature)
409	YSI (Attachable Surface Temperature - Tape on Skin)
440	Probe Extension Cord (10' Length)

Disposable, Single-Patient Use Temperature Probes

491B	STERI-PROBE, Single-Patient Use Rectal/Esophageal Probe
499B	STERI-PROBE, Single-Patient Use Skin Probe
	Contents: 10/box, 10 boxes/case
4900B	Reusable Connector Cable (for CSZ and Gaymar Unit)
4900KB	Reusable Connector Cable (for American Unit)

FIGURE (3-1) - BLANKETROL II SYSTEM ACCESSORIES